

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

BRIGHAM AND WOMEN'S HOSPITAL	:	CIVIL ACTION
INC., et al.	:	
	:	
v.	:	
	:	
TEVA PHARMACEUTICALS USA, INC.,	:	
et al.	:	NO. 08-464

MEMORANDUM

Bartle, C.J.

March 31, 2010

Brigham and Women's Hospital, Inc. ("BWH"), NPS Pharmaceuticals, Inc. ("NPS"), and Amgen Inc. ("Amgen") (collectively "plaintiffs") have sued Teva Pharmaceuticals USA, Inc., Teva Pharmaceutical Industries Ltd., and Barr Laboratories, Inc. (collectively "defendants") for infringement of pharmaceutical patents No. 6,211,244 (the "'244 patent"), 6,313,146 (the "'146 patent"), 6,011,068 (the "'068 patent"), and 6,031,003 (the "'003 patent"). Plaintiffs are each assignees of one or more of the patents in suit. These patents pertain to the pharmaceutical compound cinacalcet hydrochloride, which is used for treating secondary hyperparathyroidism and hypercalcemia, diseases common in patients on dialysis for chronic renal failure.¹

1. Plaintiff Amgen currently markets cinacalcet hydrochloride under the trade name Sensipar.

Defendants each filed an amended answer to plaintiffs' complaint in which they have denied infringement and raised the affirmative defense of inequitable conduct before the United States Patent and Trademark Office ("PTO"). In their counterclaims, defendants also seek a declaration that the patents in suit are unenforceable due to plaintiffs' inequitable conduct. Now before the court is the motion of defendants for an order finding that plaintiffs have waived the attorney-client privilege.²

I.

Defendants maintain that plaintiffs engaged in inequitable conduct during the prosecution of the '146, '068, and '003 patents when they failed to cite to the respective patent examiners the then pending application that led to the '244 patent (the "'244 Application"). According to defendants, plaintiffs intentionally withheld information regarding the '244 Application in order to extend unlawfully the patent terms of the '146, '068, and '003 patents.

To be patentable, an invention must be novel, that is, it must not be anticipated by prior art. See 35 U.S.C. § 102³;

2. We have jurisdiction under 28 U.S.C. §§ 1331 and 1338.

3. "A person shall be entitled to a patent unless (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for patent, or (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date
(continued...)

Minnesota Mining & Mfg. Co. v. Chemque, Inc., 303 F.3d 1294, 1301 (Fed. Cir. 2002). Further, "[a] patent may not be obtained ... if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains." 35 U.S.C. § 103(a). The relevant regulations require that "[e]ach individual associated with the filing and prosecution of a patent application has a duty of candor and good faith in dealing with the [PTO], which includes a duty to disclose to the Office all information known to that individual to be material to patentability." 37 C.F.R. § 1.56(a).

Inequitable conduct involves an intentional breach of the duty of candor. This occurs when an applicant, "with intent to mislead or deceive the examiner, fails to disclose material information or submits materially false information to the PTO during prosecution." Digital Control Inc. v. Charles Mach. Works, 437 F.3d 1309, 1313 (Fed. Cir. 2006). For a patent to be rendered unenforceable due to inequitable conduct, the court must find clear and convincing evidence that: (1) the applicant has failed to disclose certain material information to the PTO, and (2) such nondisclosure was done with deceptive intent. Akron

3.(...continued)
of the application for patent in the United States." 35 U.S.C. § 102.

Polymer Container Corp. v. Exxel Container, Inc., 148 F.3d 1380, 1383 (Fed. Cir. 1998).

The materiality element is judged by a "reasonable examiner" standard. McKesson Info. Solutions, Inc. v. Bridge Medical, Inc., 487 F.3d 897, 913 (Fed. Cir. 2007). Materiality is not limited to prior art, but rather "embraces any information that a reasonable examiner would substantially likely consider important in deciding whether to allow an application to issue as a patent." Akron Polymer, 148 F.3d at 1382 (internal quotation marks omitted). Even information which would not invalidate the patent may be material. McKesson Info Solutions, 487 F.3d at 913.

With regard to the intent prong, a mere showing of "intent to withhold" is insufficient. Rather, inequitable conduct requires proof of "intent to deceive." Id. This element is typically proven "by inferences drawn from facts, with the collection of inferences permitting a confident judgment that deceit has occurred." Akron Polymer, 148 F.3d at 1384. The court will balance the two factors of inequitable conduct such that "[t]he more material the omission, the less culpable the intent required, and vice versa." Halliburton Co. v. Schlumberger Tech. Corp., 925 F.2d 1435, 1439 (Fed. Cir. 1991).

Defendants sought to discover information from plaintiffs regarding their failure to disclose the '244 Application. Plaintiffs repeatedly objected to a large portion of defendants' discovery attempts on the ground that such

information, if any,⁴ is protected by the attorney-client privilege. Defendants contend that plaintiffs have waived the attorney-client privilege as a result of certain discovery responses.

In their Interrogatory No. 9, the Teva defendants asked plaintiff Amgen to "[s]tate in detail the reason(s) why [the '244 Application] was not cited to the respective patent examiners during the examination of [the patent applications leading to the '146, '068, and '003 patents]." Part of Amgen's Second Supplemental Response speaks to the materiality prong of inequitable conduct. Amgen stated that the '244 Application was not disclosed because: (1) that application was not material to the prosecution of the '068, and '003 patents as it was not prior art; and (2) the '244 patent issued after the '068 and the '003 patents, and therefore the examiner could not have refused to allow the '068 and '003 patents over the '224 Application.⁵ The remaining portion of Amgen's Second Supplemental Response to Interrogatory No. 9 deals directly with the intent prong:

[A]ll individuals who had a duty of disclosure to the United States Patent and Trademark Office for [the applications leading to the '003, '068, and '244, patents] believe in good faith that they fulfilled this duty to submit all information of which

4. Plaintiffs asserted that they had no strategy involving nondisclosure of the '244 Application and that no communications regarding such nondisclosure ever occurred.

5. In its response, Amgen states that plaintiffs are no longer asserting any claims from the '146 patent, and it therefore did not respond to the interrogatory with regard to that patent.

they were aware and acknowledged as material to patentability to the United States Patent and Trademark Office.

In support of its interrogatory answer, Amgen cited the deposition testimony of Dr. Bradford Van Wagenen, a named inventor of all four patents in suit, and that of Sheldon Heber, an attorney formerly with the law firm of Lyon & Lyon who acted as outside counsel to plaintiffs and was involved in prosecuting all of the patents in suit before the PTO.

Dr. Van Wagenen testified at his deposition:

Q. At any point in time did you consider your files of literature or patents for the calcimimetic project and whether those—that information might be material to the examination of the applications that led to the patents in suit?

A. If I would have come across a piece of literature that ended up being in my files and that I believe was relevant to these patents, I would have forwarded it to legal counsel.

Q. Did you rely on legal counsel to provide to the patent office all material information relevant to the examination of the applications of the patents in suit?

A. Absolutely.

Q. Did you have an understanding of a duty to disclose information relating to or from co-pending United States patent applications?

A. As I stated earlier, I have an understanding of my responsibility to disclose prior art, which includes patent applications, and I believe that I have done that at NPS.

Q. Do you believe that all relevant or material information was provided to the patent office during prosecution of the patents in suit?

A. I believe so.

(Pl.'s Br. 13 (citing Van Wagenen Dep. 179:10-18, 180:21-25, 184:21-185:7)) (emphasis added).

The deposition testimony of Mr. Heber provides in relevant part:

Q. Did you at any point in time ask the inventors what they knew about potential prior art to the '068 patent?

A. I don't remember. My usual practice would have been yes back then.

Q. Your usual practice would have been to discuss prior art--

A. We would ask for prior art that they thought was material.

Q. When you say that's your general practice, was that your general practice for all your applications or your general practice for applications you were handling for NPS Pharmaceuticals.

A. When I'm talking about my general practice, it's my general practice for all my applications.

Q. Do you have any exceptions that you made to that general practice of asking for prior art?

A. Not that I would do intentionally.

Q. Who made the decision as to what references would be disclosed to the Patent and Trademark Office when prosecuting these calcimimetic patent applications?

A. Who made the decision. I don't remember. What I'm getting hung up on is who provided input versus who made the decision.

Q. Who provided input?

A. That's what I don't remember, who may have provided it. I don't remember. But if I filed the paper, that means I made the final decision.

Q. As a general matter when working on applications that related to calcimimetic compounds, how was it determined what references would be cited by Lyon & Lyon to the Patent and Trademark Office.

A. ... If you're talking about references that came new to us and were made aware of [sic], we look over the references. If

needed, get input from scientists and make a determination if we thought it was material or not.

Q. What criteria did you use to determine the materiality of references that you were reviewing and deciding whether or not to cite them to the PTO?

A. I would review the reference and review the claims, and try to come to a conclusion whether or not it was material.

Q. Would it have been your policy to discuss with your clients the duty of candor with respect to their patent applications so they would know what should be disclosed to the Patent and Trademark Office?

A. Yes.

Q. Okay. But your policy with a named inventor would have been to discuss the duty of candor, correct?

A. That's correct.

Q. And your policy with respect [to] in house counsel would have been to discuss the duty of candor; is that correct?

A. Yes.

Q. Would Mr. Van Wagenen have had a duty of candor for calcimimetic patent compounds on which he was a named inventor?

A. Yes.

(Heber Dep. 43:7-44:12, 111:15-112:2, 113:7-114:5, 114:17-23, 116:8-13, 118:3-10, 119:3-6, Dec. 11, 2009) (emphasis added).

According to defendants, plaintiffs have asserted that those who had a duty of disclosure had a good-faith belief that all material information was disclosed to the PTO and that those with a duty of disclosure, such as the inventor Dr. Van Wagenen, relied on advice of counsel as a "sword" to defeat the intent prong of inequitable conduct. Defendants maintain that plaintiffs are also improperly attempting to use attorney-client

privilege as a "shield" to deflect inquiry into communications with counsel pertaining to the duty to disclose the '244 Application.

II.

Before deciding whether the attorney-client privilege has been waived, we must first determine whether to apply the law of the Federal Circuit or the law of the Circuit in which the District Court sits. In cases involving federal patent law claims, as this one does, district courts are in disagreement regarding which law pertains. Compare Chimie v. PPG Indus., Inc., 218 F.R.D. 416, 419 n.4 (D. Del. 2003), with Martin Marietta Materials, Inc. v. Bedford Reinforced Plastics, Inc., 227 F.R.D. 382, 392 (W.D. Pa. 2005).

The Federal Circuit applies the law of the circuit in which a district court sits with respect to "nonpatent issues" and applies the law of the Federal Circuit to "issues of substantive patent law." In re Spalding Sports Worldwide, Inc., 203 F.3d 800, 803 (Fed. Cir. 2000). In GFI, Inc. v. Franklin Corp., the Court of Appeals for the Federal Circuit explained this distinction as follows:

We apply regional circuit law to procedural questions that are not themselves substantive patent law issues so long as they do not (1) pertain to patent law, ... (2) bear an essential relationship to matters committed to our exclusive control by statute, or (3) clearly implicate the jurisprudential responsibilities of this court in a field within its exclusive jurisdiction.

265 F.3d 1268, 1272 (Fed. Cir. 2001) (internal citations omitted). In the context of a discovery dispute, the court stated that "'Federal Circuit law applies when deciding whether particular written or other materials are discoverable in a patent case,' at least if that issue clearly implicates substantive patent law." In re Pioneer Hi-Bred Int'l, Inc., 238 F.3d 1370, 1374 n.3 (Fed. Cir. 2001) (quoting Spalding Sports, 203 F.3d at 803).

Inequitable conduct is clearly a matter of substantive patent law. The nature of the proofs to establish and to defend against such conduct are likewise matters of substantive patent law. In our view, the issue of a waiver of the attorney-client privilege under the present circumstances is so closely related to the substantive issue of inequitable conduct and how it is defined that it too implicates substantive patent law. Accordingly, we will apply the law of the Federal Circuit. See Pioneer Hi-Bred, 238 F.3d at 1374 n.3; see also Martin Marietta, 227 F.R.D. at 391.

"The attorney-client privilege is the oldest of the privileges for confidential communications known to the common law." Upjohn Co. v. United States, 449 U.S. 383, 389 (1981); see also Mohawk Indus., Inc. v. Carpenter, 130 S. Ct. 599, 606 (2009). The privilege exists "to encourage full and frank communication between attorneys and their clients and thereby promote broader public interests in the observance of law and administration of justice." Upjohn, 449 U.S. at 389. While

communications between the attorney and the client are protected by the privilege, the facts underlying those communications are not. Id. at 395.

The party seeking to obtain privileged information has the burden of proving that a waiver has occurred. Martin Marietta, 227 F.R.D. at 389. Because the privilege belongs to the client, not the attorney, only the client may waive it. In re Seagate Tech., LLC, 497 F.3d 1360, 1372 (Fed. Cir. 2007). Generally, disclosure of the substance of a privileged communication will result in waiver, whereas disclosure of the mere fact that such communication took place will not. See Praxair, Inc. v. ATMI, Inc., 445 F. Supp. 2d 473, 480-81 (D. Del. 2006).

The Court of Appeals for the Federal Circuit has not decided whether an assertion of advice of counsel as a defense to the intent prong of inequitable conduct will result in a waiver of attorney-client privilege. Nonetheless, the court has done so in the analogous context of a claim of willful infringement.⁶ See Seagate, 497 F.3d at 1369-70; In re EchoStar Commc'ns Corp., 448 F.3d 1294, 1299 (Fed. Cir. 2006). To prove willful infringement, a plaintiff must establish that the defendant's act of infringement was intentional or at least reckless. See

6. Willful infringement is claimed by plaintiffs as a way of obtaining enhanced damages for successful claims of patent infringement. See Beatrice Foods Co. v. New England Printing & Lithographing Co., 923 F.2d 1576, 1578 (Fed. Cir. 1991).

Jurgens v. CBK, Ltd., 80 F.3d 1566, 1570 (Fed. Cir. 1996);
Seagate, 497 F.3d at 1371.

In the willful infringement context, infringers often assert the advice of counsel defense "to establish that due to reasonable reliance on advice from counsel, its continued accused activities were done in good faith." Seagate, 497 F.3d at 1369 (emphasis added). The law in the Federal Circuit is well established that a litigant who asserts reliance of the advice of counsel as a defense waives the attorney-client privilege with regard to all communications pertaining to that advice. EchoStar, 448 F.3d at 1299; Seagate, 497 F.3d at 1370.

Here, it is undisputed that the attorney-client privilege applies to communications between the inventors and their attorneys regarding disclosure of the '244 Application. Such communications between client and counsel for the purpose of obtaining legal advice clearly fall within the scope of the privilege. See Spalding Sports, 203 F.3d at 805. The issue here therefore is whether defendants have carried their burden to prove that plaintiffs waived that privilege.

Plaintiffs' discovery responses demonstrate a relationship between an inventor and his counsel in which counsel instructed the inventor regarding his duty to disclose material information to the PTO. The inventor forwarded all information which he believed to be relevant to counsel, and he relied on his counsel to make the final determination regarding whether or not

such information was material and therefore whether it would be disclosed to the PTO.

Mr. Heber testified that at the time he was prosecuting the patents in suit it was his general practice to discuss the duty of candor with, and request prior art references from, both in-house counsel and the named inventors and that he did not have any intentional exceptions to this policy. At his deposition, Dr. Van Wagenen stated, "I have an understanding of my responsibility to disclose prior art, which includes patent applications, and I believe that I have done that at NPS." Indeed, as a named inventor, Dr. Van Wagenen signed an oath or declaration acknowledging that he understood this duty. Based on the testimony of Mr. Heber, it appears that Dr. Van Wagenen's understanding of his duty of candor was, at least in part, formed by the advice he received from Mr. Heber.

Dr. Van Wagenen did not personally disclose prior art to the PTO, however. He was asked "[d]id you rely on legal counsel to provide to the patent office all material information relevant to the examination of the applications of the patents in suit?" Dr. Van Wagenen replied, "Absolutely." This testimony comports with that of Mr. Heber, who stated that he made the "final decision" regarding disclosures, and that, when he received prior art from the inventors, he would "look over the references" and "[i]f needed, get input from scientists and made a determination if ... it was material or not."

As noted above, plaintiffs state in their Second Supplemental Response to Interrogatory No. 9 that "all individuals who had a duty of disclosure ... believe in good faith that they fulfilled this duty to submit all information of which they were aware and acknowledged as material to patentability." The named inventors, such as Dr. Van Wagenen, are included in the group of "all individuals who had a duty of disclosure." See 37 C.F.R. § 1.56(c).⁷

At oral argument on the pending motion, plaintiffs' counsel confirmed that they intended to defend against the claim of inequitable conduct by calling the inventors and prosecuting attorneys at trial to testify that they believed in good faith that they disclosed to the PTO all material information of which they were aware. Dr. Van Wagenen will testify that he relied on the legal advice he received to transmit all potentially material information to counsel and will further testify that he relied on counsel to forward to the patent examiners all information that was material. The testimony of Mr. Heber will also be presented that he evaluated the forwarded information in good faith to

7. Section 1.56(a) states that "[e]ach individual associated with the filing and prosecution of a patent application has a duty of candor and good faith in dealing with the Office." 37 C.F.R. § 1.56(a). Section 1.56(c) defines "individual associated with the filing or prosecution of a patent application" as "(1) Each inventor named in the application; (2) Each attorney or agent who prepares or prosecutes the application; and (3) Every other person who is substantively involved in the preparation or prosecution of the application and who is associated with the inventor, with the assignee or with anyone to whom there is an obligation to assign the application." Id. § 1.56(c).

determine if it was indeed material and, if so, actually disclosed it to the PTO.

The discovery obtained from plaintiffs in their Second Supplemental Response to Interrogatory No. 9 as well as the testimony of Dr. Van Wagenen and Mr. Heber at their depositions constitute a waiver of the attorney-client privilege. Plaintiffs are attempting to use the advice of counsel both as a sword to defeat the intent prong of inequitable conduct and as a shield to prevent defendants from obtaining information to prove intent to withhold information from the PTO. They cannot have it both ways. See EchoStar, 448 F.3d at 1299; Seagate, 497 F.3d at 1369-70.

Having determined that plaintiffs have waived the attorney client privilege, we must now delineate the scope of that waiver. Under Federal Circuit law, "[t]he widely applied standard for determining the scope of a waiver of attorney-client privilege is that the waiver applies to all other communications relating to the same subject matter." Ft. James Corp. v. Solo Cup Co., 412 F.3d 1340, 1349 (Fed. Cir. 2005); see also Seagate, 497 F.3d at 1372. "There is no bright line test for determining what constitutes the subject matter of a waiver, rather courts weigh the circumstances of the disclosure, the nature of the legal advice sought and the prejudice to the parties of permitting or prohibiting further disclosures." Ft. James, 412 F.3d at 1349-50. When a party waives the attorney-client privilege by placing the advice of counsel at issue, the waiver

applies not only to otherwise privileged communications between the attorney and client, but also to any of the attorney's documents which reflect the substance of such advice, even if such documents would otherwise be immune from discovery under the work-product doctrine.⁸ See EchoStar, 448 F.3d 1300-04.

Here, plaintiffs have waived the attorney-client privilege as to information related to their failure to disclose the '244 Application to the patent examiners before whom were the applications leading to the '146, '068, and '003 patents. Defendants are therefore permitted to discover all information regarding this issue.⁹ To the extent that defendants need to redepose certain individuals, such as Dr. Van Wagenen and Mr. Heber, to elicit information previously withheld on the ground of attorney-client privilege, they may do so.

8. With regard to documents otherwise protected under the work-product doctrine, the waiver applies to communicative documents between client and counsel, such as opinion letters, and to any of counsel's documents which reference a communication between client and counsel, even if such documents are not themselves communications to or from a client. EchoStar, 448 F.3d at 1302-04. However, documents or portions of documents which reflect counsel's mental impressions, legal conclusions, or litigation strategy, and which were not given to the client and do not contain reference to client communications, remain protected under the work-product doctrine. Id. at 1303-04.

9. Subject to the limitation set forth above in footnote 8.